[Docket No. 1029]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

ASTRAZENECA LP and ASTRAZENECA AB, Plaintiffs, v. BREATH LIMITED, Defendant.	Consolidated Civil Action No. 08-1512 (RMB/AMD) **MEMORANDUM ORDER**
ASTRAZENECA LP and ASTRAZENECA AB, Plaintiffs, v. APOTEX, INC. and APOTEX CORP., Defendants.	
ASTRAZENECA LP and ASTRAZENECA AB, Plaintiffs, v. SANDOZ, INC., Defendant.	
ASTRAZENECA LP and ASTRAZENECA AB, Plaintiffs, v. WATSON LABORATORIES, INC., Defendant.	

Defendants Sandoz, Inc., Apotex, Inc. and Apotex Corp., and Breath Limited and Watson Laboratories, Inc. (collectively "Defendants") filed a motion to strike the expert report of Hugh D.C. Smyth, Ph.D. and the reply expert report of Peter R. Mathers. Defendants contend that these reports are not only untimely but permitting them at this late stage of the proceedings would prejudice and unduly burden both Defendants and the Court. For the reasons set forth below, the Court GRANTS Defendants' motion to strike the expert report of Hugh D.C. Smyth, Ph.D., and RESERVES decision as to Defendants' motion to strike the reply expert report of Peter R. Mathers.

This case involves Plaintiffs' invention of a once-daily inhaled corticosteroid under the name PULMICORT RESPULES®. Following remand for further proceedings related to U.S. Patent No. 7,524,834 (the "'834 Patent"), AstraZeneca LP and AstraZeneca AB (the "Plaintiffs" or "AstraZeneca") filed a motion for preliminary injunction. (Dkt. Ent. 889.) In connection with that motion, Defendants submitted inter alia the Declaration of Jeanne Moldenhauer ("Moldenhauer Decl."), a new expert, who opined that the relevant claims of the '834 Patent are invalid as obvious in light of several prior art references. (Dkt. Ents. 908-22.) Those references include U.S. Patent No. 3,962,430 to Joseph L. O'Neill

("O'Neill") and U.S. Patent No. 5,858,998 to Maria Leuschner ("Leuschner").[1] (See Moldenhauer Decl., dated February 13, 2014,

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[1] In reference to O'Neill, Moldenhauer stated:

> 50. O'Neill issued on June 8, 1976. *See* Ex. 32, O'Neill (Breath(Bud) 018210-17). O'Neill discloses the sterilization of non-electrolyte corticosteroids, including dexamethasone. *Id.* at col.1 ll.15-21 (Breath(Bud) 018211). O'Neill states that "aqueous suspensions are customarily sterilized in several ways, such as by aseptic crystallization, exposure to gases, for example ethylene oxide; . . . and by dry heat sterilization." *Id.* at col.1 ll.34-40. O'Neill also teaches that the corticosteroids "may be sterilized by autoclaving (steam under pressure) the suspended drug in an aqueous mixture of sodium chloride . . . ." *Id.* at col.2 ll.14-17.
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> 51. Before providing specific examples, O'Neill states that "[a]s one skilled in the art would appreciate, the amount of active ingredients which can be employed in the invention will depend on the specific therapeutic agent employed and the desired dosage of said therapeutic agent." *Id.* at col.3 ll.62-66 (Breath(Bud) 018212). O'Neill then continues to provide an example of a formulation containing dexamethasone acetate that is sterilized by moist heat (steam) sterilization. *Id.* at col.4 ll.5-63."
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> 132. . . . O'Neill even provides an example of a formulation containing dexamethasone acetate—a corticosteroid—that is sterilized by moist heat (steam) sterilization. *Id.* at col.4 ll.5-63 (Breath(Bud) 018212).
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> 133. A person of ordinary skill in the art would understand that a budesonide product sterilized according to the methods disclosed in O'Neil [sic] would be sterile . . . .

With respect to Leuschner, Moldenhauer explained:

> 53. Leuschner discloses pharmaceutical compositions

attached as Ex. 1 to the Declaration of Heinz J. Salmen ("Salmen Decl."), Dkt. Ent. 1030.)

After it heard argument on Plaintiffs' preliminary injunction, the Court issued a decision consolidating the motion hearing with the trial on the merits. (June 4, 2014 Opinion, Dkt.

> containing corticosteroids, including budesonide, for the treatment of hepatic diseases. *Id.* at col.1 ll.15-19; col.2 ll.1-27 (SANBUD500017). Leuschner also discloses oral preparations of the pharmaceutical compositions, including "suspensions, solutions or emulsions." *Id.* at col.3 ll.12-15, 20-23 (SANBUD500018).
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> 54. Example 3 of Leuschner is a budesonide injectable formulation. *Id.* at col.6 ll.25-36 (SANBUD500019). Although Leuschner calls the formulation a "solution," (*id.* at col.6 l.35), the budesonide injectable solution is created using an Ultraturrax, (*id.* at col.6 ll.33-35), which is used to create suspensions, thereby teaching a person skilled in the art that the formulation in Example 3 of Leuschner is, in actuality, a suspension, not a solution. The suspension is then sterilized for 20 minutes at 121°C. *Id.* at col.6 ll.35-36.
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> * * *
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> 161. A person of ordinary skill in the art would understand that Leuschner's disclosed method for sterilizing corticosteroid drug products would inherently pass a USP <71> test. . . .
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> 162. . . . [A] person of ordinary skill in the art would have been motivated to use the sterilization method disclosed in Leuschner to create a sterile budesonide suspension, and that person would have had a reasonable expectation that the Leuschner process would successfully sterilize budesonide.

(Moldenhauer Decl. ¶¶ 50-51, 53-54, 132-33, 161-62.)

Ent. 980.) The Opinion addressed both the O'Neill and Leuschner prior art references raised by Defendants, noting that the record would need to be further developed. (Id. at 39-40, 41 n.25.) The Court concluded that the remaining question "is whether a POSA would have had a reasonable expectation of using well-known solutions to these traditional [sterilization] processes to produce a pharmaceutically acceptable product that met the criteria of sterility." (Id. at 43.)

According to the Scheduling Order entered on June 13, 2014, opening expert reports were due on July 3, 2014, responsive expert reports on August 1, 2014, and reply expert reports addressing issues raised in the responsive expert reports were due on August 29, 2014. (Dkt. Ent. 991.)

On July 3, 2014, Defendants submitted the Opening Expert Report of Jeanne Moldenhauer (the "Moldenhauer Opening Report"), in which Moldenhauer explained – in language nearly identical to her February Declaration - that O'Neill discloses types of sterilization for non-electrolyte corticosteroids and provides "an example of a formulation containing dexamethasone acetate and sodium chloride (amongst other ingredients) that is sterilized by moist heat (steam) sterilization." (Moldenhauer Opening Report, Dkt. Ent. 1047, ¶ 58.) The example to which she refers in this paragraph of her Declaration is Example 1 of O'Neill. (Id.)

Moldenhauer also explained that Leuschner discloses pharmaceutical compositions such as suspensions and that Example 3 of Leuschner is a budesonide injectable formulation. (Id. at ¶¶60-62.)[2] [As discussed below, Example 1 of O'Neill and Example 3 of Leuschner are the subjects of Smyth's testing data.]

On August 1, 2014, AstraZeneca's second round of experts included reports of Drs. Robert O. Williams, III, James Akers, and George Zhanel, who responded to the Moldenhauer Opening Report and specifically addressed Leuschner and O'Neill. (Defs.' Br. at 8.) In particular, Drs. William and Akers concluded that neither Example 3 of Leuschner nor Example 1 of O'Neill discloses a pharmaceutically acceptable inhalation product. (Salmen Decl., Exs. 9 & 10.) None of the experts' reports mentioned Smyth.

a. Smyth Report

On August 29, 2014, AstraZeneca served upon Defendants the expert report of Smyth (the "Smyth Report"), who had never previously been mentioned as an expert. Attached to the Smyth Report is a declaration purporting to replicate Example 3 of Leuschner and Example 1 of O'Neill. (See Ex. 1, attached to the

[2] In addition, Defendants submitted the Second Opening Report of Paul B. Myrdal, Ph.D., which refers to the Moldenhauer Opening Report and the prior art references cited therein. (Salmen Decl., Ex. 4.) He opines that a POSA would have a reasonable expectation of successfully preparing a sterile budesonide powder and suspension in light of these prior art references.

Declaration of Jay I. Alexander ("Alexander Decl."), Dkt. Ent. 1037.) Smyth concludes that "[t]he Leuschner method clearly results in a visibly uneven, clumpy mixture that would not be pharmaceutically acceptable, with or without autoclaving." (Id. at ¶ 30.) As to O'Neill, Smyth concludes that the method "results in a significant increase in particle size of the raw budesonide that would not be pharmaceutically acceptable." (Id. at ¶ 49.) Interestingly, the Smyth Report does not purport to be responsive to any of Defendants' expert reports.

Defendants argue that the Smyth Report should be stricken as untimely and outside the scope of discovery contemplated by the Scheduling Order. In response, AstraZeneca argues that the Smyth Report is timely as it was submitted in reply to the Responsive Expert Report of Moldenhauer served on August 1, 2014. (Alexander Decl., Ex. 8.) The Responsive Report addresses the opinions contained within AstraZeneca's opening expert reports regarding the objective indicia of non-obviousness, on which AstraZeneca bears the burden of presenting evidence. In the Responsive Report, Moldenhauer opined:

> As I explained in my Opening Report (¶¶ 145-46), I am not aware of any evidence that anyone outside of AstraZeneca was skeptical that it would be possible to attempt to make a sterile budesonide suspension. To the contrary, the prior art references discussed in my Opening Report, particularly O'Neill . . . [and] Leuschner . . . indicate the opposite: a person of ordinary skill in the art would have had a reasonable

> expectation of creating a sterile budesonide composition (powder or suspension) and would not have been skeptical of his/her success.

(Alexander Decl., Ex. 8 ¶ 36.) She similarly concluded that AstraZeneca's sterilization results were not unexpected because of the teachings of these references. (Id. ¶¶ 53, 57.) Moldenhauer further opined that there is no evidence that others had tried and failed to create a sterile budesonide suspension; rather, "[o]thers in the art made sterile corticosteroids and corticosteroid suspensions (O'Neill), including budesonide suspensions (Leuschner, Clark, Harris)." (Id. at ¶¶ 46, 48.) According to AstraZeneca, Moldenhauer's Responsive Report – apparently for the first time - "squarely put at issue whether Leuschner and O'Neill had actually achieved the results alleged to have been made in their patent disclosure." (Pl.'s Opp. at 3.)

It is clear to the Court that the Moldenhauer Opening Report preemptively addressed the indicia of non-obviousness and contains nearly identical opinions regarding the impact of Leuschner and O'Neill on the unexpected results (Dkt. Ent. 1047 ¶¶ 136-148) and industry skepticism (id. at ¶ 146). Moldenhauer also opined in her Opening Report that she was unaware of evidence that others had tried to create a sterile budesonide suspension but failed. (Id. at ¶ 144.) Moldenhauer refers to the O'Neill and Leuschner references throughout these opinions, and

concludes that in light of these references a POSA would have expected to successfully create a sterile BIS product. Notably, the Moldenhauer Opening Report specifically discusses Example 1 of O'Neill and Example 3 of Leuschner – the very examples that Smyth purports to have recreated. Thus, setting aside the fact that AstraZeneca has been aware of the importance of the Leuschner and O'Neill prior art references (including the examples that are the subject of Smyth's testing) since Moldenhauer's February 2014 Declaration, the scope of her opinions regarding these references was fully disclosed to AstraZeneca in Moldenhauer's Opening Report served on July 3 pursuant to the Scheduling Order, not in her Responsive Report. Indeed, her Responsive Report merely reiterates and refers to portions of her Opening Report. Even more significantly, while Smyth does not provide any dates for his experiments, Exhibit 22 to his Declaration suggests they were conducted sometime in mid-July – weeks before Moldenhauer's Responsive Report that supposedly put this data at issue. (Salmen Decl., Ex. 12 at Ex. 22.) Hence, AstraZeneca only feigns surprise.

AstraZeneca's failure to disclose Smyth until the third round of expert reports and just a few weeks prior to the close of expert discovery and commencement of trial is untimely and violates the Scheduling Order. Expert disclosures are governed by

Federal Rule of Civil Procedure 26, which requires parties to disclose the identity of potential expert witnesses and to provide a written report containing the experts' opinions as well as the facts and data relied upon to form those opinions. Fed. R. Civ. P. 26(a)(2)(B). Rule 26 further provides "A party must make these disclosures at the times and in the sequence that the court orders. Absent a stipulation or a court order, the disclosures must be made: . . . (ii) if the evidence is intended solely to contradict or rebut evidence on the same subject matter identified by another party under Rule 26(a)(2)(B) or (C), within 30 days after the other party's disclosure." Fed. R. Civ. P. 26(a)(2)(D). Under the Scheduling Order in place, responsive expert reports were due on August 1, 2014, while reply expert reports "addressing issues raised in responsive expert reports" were due on August 29, 2014. (Dkt. Ent. 991.)

In deciding whether to exclude evidence, the Third Circuit instructs courts to consider the following factors:

> (1) "the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified" or the excluded evidence would have been offered; (2) "the ability of that party to cure the prejudice"; (3) the extent to which allowing such witnesses or evidence would "disrupt the orderly and efficient trial of the case or of other cases in the court"; (4) any "bad faith or willfulness in failing to comply with the court's order"; and (5) the importance of the excluded evidence.

ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 298 (3d Cir. 2012)

(quoting Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 905 (3d Cir. 1977), overruled on other grounds by Goodman v. Lukens Steel Co., 777 F.2d 113 (3d Cir. 1985)).

The Court finds that permitting the Smyth Report would inure to the prejudice of Defendants. The Report attempts to rebut the teachings of prior art references, and corresponding expert opinions, that were known to AstraZeneca in February 2014 and certainly no later than the exchange of expert reports on July 3, 2014. Rather than respond to Moldenhauer's opinions by August 1, 2014, pursuant to the applicable Scheduling Order, AstraZeneca waited until August 29, 2014 – just weeks before the close of discovery and the commencement of trial - before suddenly springing upon Defendants new experimental data. In the three weeks prior to the close of discovery, the parties have deposed numerous experts and have been preparing for an October 6, 2014 trial date, leaving Defendants insufficient time to address the new experimental data proffered by a previously-undisclosed expert.

Although AstraZeneca contends that any prejudice to Defendants can be cured by permitting Defendants to depose Smyth prior to his trial testimony, this suggestion does not adequately address the harm to Defendants if the Smyth Report is permitted. At this late juncture, after the close of expert discovery,

Defendants are unable to hire an expert of their own to conduct the tests, or to otherwise adequately rebut Smyth's results. Providing Defendants with sufficient time to address Smyth's new evidence would require delaying the trial in a case that has already spanned years. In addition, while AstraZeneca is prejudiced by the exclusion of evidence seemingly helpful to it, such prejudice was of its own making and could easily have been avoided by the timely disclosure of Smyth.

AstraZeneca's late disclosure of Smyth is simply inexcusable, and AstraZeneca's reasons for such lateness are disingenuous. Smyth addresses issues that were laid out explicitly in the Moldenhauer Opening Report – not issues raised for the first time in the Responsive Report as AstraZeneca contends. It is clear to this Court from a review of both of Moldenhauer's reports that she addresses the secondary indicia of non-obviousness in almost identical form. Moreover, in her Opening Report, she discusses the teachings of O'Neill Example 1 and Leuschner Example 3 that AstraZeneca now attempts to rebut through reliance on the Smyth Report. AstraZeneca's argument that the second report entitles it to a rebuttal is unacceptable. Furthermore, it appears from the record that Smyth may have been engaged to conduct these experiments as early as mid-July – prior to receiving the Responsive Report that AstraZeneca cites as the

basis for Smyth's retention. It is thus quite suspect that Smyth began these experiments only a few weeks after receiving the Moldenhauer Opening Report that addresses the methods Smyth purportedly employed in conducting his experiments. At the very least, AstraZeneca should have disclosed its intention to rely upon Smyth, as well as the scope of his experiments, in response to Moldenhauer's Opening Report.

As to the last factor, the purported results of Smyth's experiment clearly constitute important evidence for AstraZeneca and may support its argument regarding the objective indicia of non-obviousness. See Mintz v. Dietz & Watson, Inc., 679 F.3d 1372, 1378 (Fed. Cir. 2012) (noting objective indicia "are powerful tools for courts faced with the difficult task of avoiding subconscious reliance on hindsight") (citations omitted). However, this factor alone does not save AstraZeneca. Notably, the Smyth Report does not constitute the only such evidence of non-obviousness, nor even the only rebuttal evidence to Moldenhauer's opinions. Accordingly, there is no fundamental unfairness in excluding Smyth's Report as AstraZeneca will still have the opportunity to proffer other rebuttal evidence addressing Moldenhauer's opinions, including the testimony of Drs. Williams and Akers, who opined at length upon the Leuschner and O'Neill references. (See Salmen Decl., Exs. 8 & 9); cf. ABB

Air Preheater, Inc. v. Regenerative Envt'l. Equip. Co., Inc., 167 F.R.D. 668, 672 (D.N.J. 1996) ("'Notwithstanding Rule 37(c), the district court may be found to have abused its discretion if [its] exclusion of testimony results in fundamental unfairness in the trial of the case.'") (citations omitted). Therefore, the Court finds that the factors set forth in Pennypack justify exclusion of the Smyth Report.

b. Mathers Reply

Defendants also seek to strike the Reply Expert Report of Peter R. Mathers ("Mathers Reply") (Salmen Decl., Ex. 13). AstraZeneca disclosed Mathers for the first time on August 11, 2014, and served his expert report on August 29, 2014. The Court's decision as to Defendants' motion to strike this report is reserved and will require further briefing by AstraZeneca. In particular, AstraZeneca shall address why it should not be judicially estopped from taking a position that appears to contradict its earlier position in this litigation. Indeed, the Court believed that the issue of the FDA moving towards requiring the sterilization of suspensions was undisputed.[3] The Mathers'

[3] May 9, 2014 Tr. at 36-37 ("THE COURT: And am I right that the regulation, that the proposed regulation in 1991 dealt with solutions but there is no disagreement in the industry that everyone expected it to apply to suspensions eventually? MR. RAKOCZY: Correct, your Honor. It used the term 'solution' originally, but Dr. Muhvich testified that everyone in the industry knew that that meant all aqueous based inhalation

Reply, however, seems to contradict what AstraZeneca represented to the Court in its submissions.[4] (See Dkt. Ent. 890 at 20 ("Due to recalls of other drugs, however, the FDA was moving toward requiring sterilization for solutions and inhaled suspensions.") (citations omitted); Dkt. Ent. 977 at 5 ("At the time of the invention, there were well-known reasons to *try* to make a sterile budesonide suspension. In the 1980s, contaminated inhalation products had caused widely publicized patient deaths, ultimately prompting the FDA to demand that all new inhalation products be manufactured sterile.").)

Accordingly,

IT IS ON THIS **26th** day of **September 2014**,

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products. THE COURT: Is that disputed in this record? MR. RAKOCZY: No one has rebutted that from Astra. There was no document rebutting that, and I don't know if there could be given the fact that we have in the file history FDA's statement saying you better make this sterile. It was known in the industry to skilled persons. And as a matter of law, your Honor, motivation doesn't have to be in a publication; it can be, but it can come from just the general knowledge of the skilled person, and I don't think there is a serious dispute that everybody knew that you would have to make it sterile. I mean, Dr. Williams didn't fight on that at all, he agreed that motivation had been around for awhile. I think he said ten years before the patent. So I don't think it's in serious dispute. THE COURT: Okay."). At no time during the forgoing colloquy did AstraZeneca disabuse the Court of its understanding.

[4] This is not the first time this Court has had to "address[] the ever-shifting arguments made by AstraZeneca." (June 4, 2014 Opinion at 20.)

ORDERED that Defendants' motion to strike the expert report of Hugh D.C. Smyth, Ph.D. is hereby GRANTED; and it is further

ORDERED that the Court will RESERVE decision as to Defendants' motion to strike the reply expert report of Peter R. Mathers; and it is further

ORDERED that on or before October 3, 2014, AstraZeneca shall SHOW CAUSE why AstraZeneca should not be judicially estopped from taking a position that appears to be directly contradicted by AstraZeneca's prior position before this Court (and which this Court believed to be undisputed).

s/Renée Marie Bumb
RENÉE MARIE BUMB
UNITED STATES DISTRICT JUDGE